Missouri Department of Health & Senior Services

Health Update:

Updated Guidance on Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)

March 9, 2020

This document will be updated as new information becomes available. The current version can always be viewed at http://www.health.mo.gov.

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Health Update
March 9, 2020

FROM: **RANDALL W. WILLIAMS, MD, FACOG**
DIRECTOR

SUBJECT: **Updated Guidance on Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)**

Distributed via the CDC Health Alert Network
March 08, 2020, 8:20 PM ET
CDCHAN-00429

Summary

The Centers for Disease Control and Prevention (CDC) continues to closely monitor and respond to the COVID-19 outbreak caused by the novel coronavirus, SARS-CoV-2.

This CDC Health Alert Network (HAN) Update highlights guidance and recommendations for evaluating and identifying patients who should be tested for COVID-19 that were shared on March 4, 2020, on the CDC COVID-19 website at https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html. It supersedes the guidance and recommendations provided in CDC's HAN 428 distributed on February 28, 2020.

The outbreak that began in Wuhan, Hubei Province, has now spread throughout China and to 101 other countries and territories, including the United States. As of March 8, 2020, there were more than 105,000 cases reported globally. In addition to sustained transmission in China, there is now community spread in several additional countries. CDC has updated travel guidance to reflect this information (https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html).

As of March 7, 2020, there were a total of 213 cases within the United States, of which, 49 were among repatriated persons from high-risk settings. Among the other 164 cases that were diagnosed in the United States, 36 were among persons with a history of recent travel in China or other affected areas, and 18 were persons in close contact with another confirmed COVID-19 patient (i.e., person-to-person spread); 110 cases are currently under investigation. During the week of February 23, community spread of the virus that causes COVID-19 was reported in California in two places, Oregon, and Washington. Community spread in Washington resulted in the first reported case of COVID-19 in a healthcare worker, and the first outbreak in a long-term care facility. The first death due to COVID-19 was also reported from Washington; there have now been 11 reported deaths in the U.S. from COVID-19. As of March 7, 2020, COVID-19 cases had been reported by 19 states. CDC will continue to work with state and local health departments, clinicians, and laboratorians to identify and respond to other cases of COVID-19, especially those with an unknown source of infection, to limit further community spread. The most recent update describing COVID-19 in the United States can be found at https://www.cdc.gov/coronavirus/2019ncov/cases-in-us.html.

Recognizing persons who are at risk for COVID-19 is a critical component of identifying cases and preventing further transmission. With expanding spread of COVID-19, additional areas of geographic risk are being identified and the criteria for considering testing are being updated to reflect this spread. In addition, with increasing access to testing, the criteria for testing for COVID-19 have been expanded to include more symptomatic persons, even in the absence of travel history to affected areas or known exposure to another case, to quickly detect and respond to community spread of the virus in the United States.

Criteria to Guide Evaluation and Laboratory Testing for COVID-19 at the Missouri State Public Health Laboratory

COVID-19 diagnostic testing is available through the Missouri State Public Health Laboratory for individuals meeting the criteria listed below. Clinicians should note that the geographic locations listed are likely to change with the epidemiologic picture of the outbreak. To request testing for patients that meet one of these criteria, please contact your local public health agency, or the Missouri Department of Health and Senior Services (DHSS) at 800-392-0272 (24/7).

Interim Missouri COVID-19 Person Under Investigation (PUI) Definition
Updated March 9, 2020

Clinical Features		Epidemiologic Risk
Fever[1] **or** signs/symptoms of lower respiratory illness (e.g. cough or shortness of breath)	AND	Any person, including healthcare workers[2], who has had close contact[3] with a laboratory-confirmed[4] COVID-19 patient within 14 days of symptom onset
Fever[1] **and** signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath) requiring hospitalization	AND	A history of travel from affected geographic areas[5] (see below) within 14 days of symptom onset
Fever[1] with severe acute lower respiratory illness (e.g., pneumonia, ARDS) requiring hospitalization and without alternative explanatory diagnosis (e.g., influenza)[6]	AND	No source of exposure has been identified
Fever[1] **and** signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath) without alternative explanatory diagnosis (e.g., influenza), not hospitalized or considered severe	AND	A history of travel from affected geographic areas[5] (see below) within 14 days of symptom onset

Areas with Sustained (Ongoing) Transmission		
International		US
China Iran Italy	Japan South Korea	King County/Seattle, Washington, USA

[1]Fever may be subjective or confirmed

[2]For healthcare personnel, testing may be considered if there has been exposure to a person with suspected COVID-19 without laboratory confirmation. Because of their often extensive and close contact with vulnerable patients in healthcare settings, even mild signs and symptoms (e.g., sore throat) of COVID-19 should be evaluated among potentially exposed healthcare personnel. Additional information is available in CDC's Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease 2019 (COVID-19).

[3]Close contact is defined as—

a) being within approximately 6 feet (2 meters) of a COVID-19 case for a prolonged period of time; close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case

– or –

b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on)

If such contact occurs while not wearing recommended personal protective equipment or PPE (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection), criteria for PUI consideration are met.

Additional information is available in CDC's updated Interim Infection Prevention and Control Recommendations for Patients with Confirmed COVID-19 or Persons Under Investigation for COVID-19 in Healthcare Settings.

Data to inform the definition of close contact are limited. Considerations when assessing close contact include the duration of exposure (e.g., longer exposure time likely increases exposure risk) and the clinical symptoms of the person with COVID-19 (e.g., coughing likely increases exposure risk as does exposure to a severely ill patient). Special consideration should be given to healthcare personnel exposed in healthcare settings as described in CDC's Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with COVID-19.

[4]Documentation of laboratory-confirmation of COVID-19 may not be possible for travelers or persons caring for COVID-19 patients in other countries.

[5]Affected areas are defined as geographic regions where sustained community transmission has been identified. Relevant affected areas will be defined as a country with at least a CDC Level 2 Travel Health Notice. See all COVID-19 Travel Health Notices.

[6]Category includes single or clusters of patients with severe acute lower respiratory illness (e.g., pneumonia, ARDS) of unknown etiology in which COVID-19 is being considered.

National priorities for COVID-19 Testing at Commercial Laboratories

COVID-19 diagnostic testing, authorized by the Food and Drug Administration under an Emergency Use Authorization (EUA), is becoming available in clinical laboratories. This additional testing capacity will allow clinicians to consider COVID-19 testing for a wider group of symptomatic patients than can be tested through the Missouri State Public Health Laboratory.

Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Most patients with confirmed COVID-19 have developed fever[1] and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). Priorities for testing may include:

1. Hospitalized patients who have signs and symptoms compatible with COVID-19 in order to inform decisions related to infection control.
2. Other symptomatic individuals such as, older adults (age ≥ 65 years) and individuals with chronic medical conditions and/or an immunocompromised state that may put them at higher risk for poor outcomes (e.g., diabetes, heart disease, receiving immunosuppressive medications, chronic lung disease, chronic kidney disease).
3. Any persons including healthcare personnel[2], who within 14 days of symptom onset had close contact[3] with a suspect or laboratory-confirmed[4] COVID-19 patient, or who have a history of travel from affected geographic areas[5] (see below) within 14 days of their symptom onset.

Clinicians are strongly encouraged to test for other causes of respiratory illness (e.g., influenza). Mildly ill patients should be encouraged to stay home and contact their healthcare provider by phone for guidance about clinical management. Patients who have severe symptoms, such as difficulty breathing, should seek care immediately. Older patients and individuals who have underlying medical conditions or are immunocompromised should contact their physician early in the course of even mild illness.

International Areas with Sustained (Ongoing) Transmission
Last updated March 8, 2020
(https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html)

- China: Level 3 Travel Health Notice (https://wwwnc.cdc.gov/travel/notices/warning/novelcoronavirus-china)
- Iran: Level 3 Travel Health Notice (https://wwwnc.cdc.gov/travel/notices/warning/coronavirus-iran)
- Italy: Level 3 Travel Health Notice (https://wwwnc.cdc.gov/travel/notices/warning/coronavirus-italy)
- Japan: Level 2 Travel Health Notice (https://wwwnc.cdc.gov/travel/notices/alert/coronavirusjapan)
- South Korea: Level 3 Travel Health Notice (https://wwwnc.cdc.gov/travel/notices/warning/coronavirus-south-korea)

Recommendations for Reporting, Laboratory Testing, and Specimen Collection
Clinicians should immediately implement recommended infection prevention and control practices (https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html) if a patient is suspected of having COVID-19. They should also notify infection control personnel at their healthcare facility and their state or local health department if it is suspected that a patient may have COVID-19. State health departments that have identified a person suspected of having COVID-19 or a laboratory confirmed case should complete a PUI and Case Report form through the processes identified on CDC's Coronavirus Disease 2019 website (https://www.cdc.gov/coronavirus/2019-ncov/php/reporting-pui.html). If specimens are sent to CDC for laboratory testing, state and local health departments can contact CDC's Emergency Operations Center (EOC) at 770-488-7100 for assistance with obtaining, storing, and shipping, including after hours, on weekends, and holidays

Guidance for the identification and management of potentially exposed contacts of a confirmed case of COVID-19 can be found in Interim US Guidance for Risk Assessment and Public Health Management of Persons with Potential Coronavirus Disease 2019 (COVID-19) Exposures: Geographic Risk and Contacts of Laboratory-confirmed Cases (https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html).

Separate guidance for the management of potentially exposed contacts of a COVID-19 case who are healthcare personnel is provided in Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with

Coronavirus Disease (COVID-19) (https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-riskassesment-hcp.html).

For initial diagnostic testing for COVID-19, CDC recommends collecting and testing upper respiratory tract specimens (nasopharyngeal AND oropharyngeal swabs). CDC also recommends testing lower respiratory tract specimens, if available. For patients who develop a productive cough, sputum should be collected and tested for SARS-CoV-2. The induction of sputum is not recommended. For patients for whom it is clinically indicated (e.g., those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage sample should be collected and tested as a lower respiratory tract specimen. Specimens should be collected as soon as possible once a person has been identified for testing, regardless of the time of symptom onset. See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for COVID-19 (https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html) and Biosafety FAQs for handling and processing specimens from suspected cases and PUIs (https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html).

[1]Fever may be subjective or confirmed

[2]For healthcare personnel, testing may be considered if there has been exposure to a person with suspected COVID-19 without laboratory confirmation. Because of their often extensive and close contact with vulnerable patients in healthcare settings, even mild signs and symptoms (e.g., sore throat) of COVID-19 should be evaluated among potentially exposed healthcare personnel. Additional information is available in CDC's Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease 2019 (COVID-19) (https://www.cdc.gov/coronavirus/2019ncov/hcp/guidance-risk-assesment-hcp.html).

[3]Close contact is defined as—

a) being within approximately 6 feet (2 meters) of a COVID-19 case for a prolonged period; close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case

– or –

b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on)

If such contact occurs while not wearing recommended personal protective equipment (PPE) (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection), criteria for PUI consideration are met.

Additional information is available in CDC's updated Interim Infection Prevention and Control Recommendations for Patients with Confirmed COVID-19 or Persons Under Investigation for COVID-19 in Healthcare Settings (https://www.cdc.gov/coronavirus/2019-ncov/infection-control/controlrecommendations.html).

Data to inform the definition of close contact are limited. Considerations when assessing close contact include the duration of exposure (e.g., longer exposure time likely increases exposure risk) and the clinical symptoms of the person with COVID-19 (e.g., coughing likely increases exposure risk as does exposure to a severely ill patient). Special consideration should be given to healthcare personnel exposed in healthcare settings as described in CDC's Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with COVID-19 (https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-riskassesment-hcp.html).

[4]Documentation of laboratory-confirmation of COVID-19 may not be possible for travelers or persons caring for COVID-19 patients in other countries.

[5]Affected areas are defined as geographic regions where sustained community transmission has been identified. For a list of relevant affected areas, see Coronavirus Disease 2019 Information for Travel (https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html).

For More Information
More information is available at the COVID-19 website: https://www.cdc.gov/coronavirus/2019ncov/index.html.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

Categories of Health Alert Network messages:
Health Alert Requires immediate action or attention; highest level of importance
Health Advisory May not require immediate action; provides important information for a specific incident or situation
Health Update Unlikely to require immediate action; provides updated information regarding an incident or situation **HAN Info Service** Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, epidemiologists, HAN coordinators, and clinician organizations##

Missouri Department of Health & Senior Services

Health Update:

Criteria to Guide Evaluation and Laboratory Testing for COVID-19

March 24, 2020

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Health Update
March 24, 2020

FROM: **RANDALL W. WILLIAMS, MD, FACOG**
DIRECTOR

SUBJECT: **Update: Criteria to Guide Evaluation and Laboratory Testing for COVID-19 (updates underlined)**

Issued March 22, 2020

Summary

Testing for COVID-19 is available through the Missouri State Public Health Laboratory (SPHL) as well as commercial clinical laboratories. Clinicians who wish to submit specimens to the SPHL must submit a Missouri Patient Under Investigation (PUI) and Case Report Form and a Virology Test Request **for each approved patient**. For more information and to access the forms, please visit the SPHL Novel Coronavirus webpage at https://health.mo.gov/lab/ncov.php. COVID-19 testing for asymptomatic individuals through any laboratory is not recommended. **To request testing through the SPHL, providers should call the Department of Health and Senior Services Hotline at 877-435-8411.**

Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Most patients with confirmed COVID-19 have developed fever[1] and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). Priorities for testing may include:

1. Hospitalized patients who have signs and symptoms compatible with COVID-19 in order to inform decisions related to infection control.
2. Symptomatic residents of congregate living facilities that house adults ages 65 or older and individuals with chronic medical conditions and/or an immunocompromised state that may put them at higher risk for poor outcomes (e.g., diabetes, chronic heart disease, such as heart failure, receiving immunosuppressive medications, chronic lung disease, chronic kidney disease).
3. Any persons including healthcare personnel[2], who within 14 days of symptom onset had close contact[3] with a suspect COVID-19 patient with pending laboratory testing or laboratory-confirmed[4] COVID-19 patient.

There are epidemiologic factors that may also help guide decisions about COVID-19 testing. Documented COVID-19 infections in a jurisdiction and known community transmission may contribute to an epidemiologic risk assessment to inform testing decisions. Clinicians are strongly encouraged to test for other causes of respiratory illness (e.g., influenza).

Mildly ill patients should be encouraged to stay home and contact their healthcare provider by phone for guidance about clinical management. Patients who have severe symptoms, such as difficulty breathing, should seek care immediately. Older patients and individuals who have underlying medical conditions or are immunocompromised should contact their physician early in the course of even mild illness.

FOR PERSONS with COVID-19 UNDER HOME ISOLATION:
The decision to discontinue home isolation should be made in the context of local circumstances. Options now include both 1) a time-since-illness-onset and time-since-recovery (non-test-based) strategy, and 2) a test-based strategy.

Time-since-illness-onset and time-since-recovery strategy (non-test-based strategy) - Persons with COVID-19 who have symptoms and were directed to care for themselves at home may discontinue home isolation under the following conditions:

- At least 3 days (72 hours) have passed *since recovery* defined as resolution of fever without the use of fever-reducing medications **and** improvement in respiratory symptoms (e.g., cough, shortness of breath); **and,**
- At least 7 days have passed *since symptoms first appeared*.

This recommendation will prevent most, but may not prevent all instances of secondary spread. The risk of transmission after recovery, is likely very substantially less than that during illness.

Previous recommendations for a test-based strategy remain applicable; however, a test-based strategy is contingent on the availability of ample testing supplies and laboratory capacity as well as convenient access to testing.

Individuals with laboratory-confirmed COVID-19 who have not had any symptoms may discontinue home isolation when at least 7 days have passed since the date of their first positive COVID-19 diagnostic test and have had no subsequent illness.

Return to Work Criteria for HCP with Confirmed or Suspected COVID-19
Two recommended options are listed below for healthcare facilities that have employees returning to work after COVID-19 illness.

1. Non-test-based strategy. Exclude from work until:
    a. At least 3 days (72 hours) have passed *since recovery* defined as resolution of fever without the use of fever-reducing medications **and** improvement in respiratory symptoms (e.g., cough, shortness of breath); **and**,
    b. At least 7 days have passed *since symptoms first appeared.*
2. Test-based strategy. Exclude from work until:
    a. Resolution of fever without the use of fever-reducing medications **and**
    b. Improvement in respiratory symptoms (e.g., cough, shortness of breath), **and**
    c. Negative results of an FDA Emergency Use Authorized molecular assay for COVID-19 from at least two consecutive nasopharyngeal swab specimens collected ≥24 hours apart (total of two negative specimens)[1]. See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for 2019 Novel Coronavirus (2019-nCoV).

If HCP were never tested for COVID-19 but have an alternative diagnosis (e.g., tested positive for influenza), criteria for return to work should be based on that diagnosis.

Return to Work Practices and Work Restrictions
After returning to work, HCP should:

- Wear a facemask at all times while in the healthcare facility until all symptoms are completely resolved or until 14 days after illness onset, whichever is longer
- Be restricted from contact with severely immunocompromised patients (e.g., transplant, hematology-oncology) until 14 days after illness onset
- Adhere to hand hygiene, respiratory hygiene, and cough etiquette in CDC's interim infection control guidance (e.g., cover nose and mouth when coughing or sneezing, dispose of tissues in waste receptacles)
- Self-monitor for symptoms, and seek re-evaluation from occupational health if respiratory symptoms recur or worsen

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[1] Fever may be subjective or confirmed.

[2] For healthcare personnel, testing may be considered if there has been exposure to a person with suspected COVID-19 without laboratory confirmation. Because of their often extensive and close contact with vulnerable patients in healthcare settings, even mild signs and symptoms (e.g., sore throat) of COVID-19 should be evaluated among potentially exposed healthcare personnel. Additional information is available in CDC's Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease 2019 (COVID-19).

[3] Close contact is defined as—
a) being within approximately 6 feet (2 meters) of a COVID-19 case for a prolonged period of time; close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case
– or –
b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on)
If such contact occurs while not wearing recommended personal protective equipment or PPE (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection), criteria for PUI consideration are met.

Additional information is available in CDC's updated Interim Infection Prevention and Control Recommendations for Patients with Confirmed COVID-19 or Persons Under Investigation for COVID-19 in Healthcare Settings.

Data to inform the definition of close contact are limited. Considerations when assessing close contact include the duration of exposure (e.g., longer exposure time likely increases exposure risk) and the clinical symptoms of the person with COVID-19 (e.g., coughing likely increases exposure risk as does exposure to a severely ill patient). Special consideration should be given to healthcare personnel exposed in healthcare settings as described in CDC's Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with COVID-19.

[4] Documentation of laboratory-confirmation of COVID-19 may not be possible for travelers or persons caring for COVID-19 patients in other countries.

Missouri Department of Health & Senior Services

Health Update:

Update: Reporting COVID-19 Cases

April 6, 2020

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Health Update
April 6, 2020

FROM: RANDALL W. WILLIAMS, MD, FACOG
DIRECTOR

SUBJECT: Update: Reporting COVID-19 Cases

Background

The Missouri Department of Health and Senior Services (DHSS) has been working with partners across the state to respond to the COVID-19 pandemic. As of today's report, 2,722 cases of COVID-19 have been reported in Missouri. Several waivers have been granted to statute and rule alike in order to better serve Missourians during this unprecedented event. The purpose of this update is to provide healthcare providers a resource that pulls together multiple waivers that are intended to ensure a robust surveillance system for COVID-19. The rule changes and waivers include the reporting of COVID-19 to DHSS, duplicate reporting of negative results by hospitals, and the reporting of COVID-19 deaths to DHSS.

Reporting Rules Changes and Waivers

Disease Reporting

The State of Missouri has waived certain aspects of communicable disease reporting rules as they apply to COVID-19. 19 CSR 20-20.020 (1), (6), and (8) have been be waived to the extent necessary to have all positive and negative test results for COVID-19 sent only to DHSS. This waiver removes the option for the reporter to send such results to either the local health authority or DHSS. This will remain in place throughout the State of Emergency. This waiver does not limit communication between healthcare providers and local public health agencies (LPHAs) that are investigating COVID-19 cases. This waiver does not prohibit reporting to LPHAs. However, it does mandate that providers must report to DHSS.

Negative Result Reporting by Laboratories Only

Missouri 19 CSR 20-20.020(6) has been waived to the extent that it requires duplicative reporting to DHSS of negative test results for 2019 Novel Coronavirus (2019-nCoV) by a hospital and the separate laboratory that conducted the testing. Under this waiver, when the testing is conducted outside the hospital by a separate laboratory that must also report the result to the Department, only the laboratory must make the report. This waiver does not apply to the reporting of cases of COVID-19.

Reporting Death Associated with SARS CoV-2 or Clinically Diagnosed COVID-19

Deaths of individuals with positive laboratory tests for SARS CoV-2 or clinically diagnosed COVID-19 are reportable to DHSS within twenty-four (24) hours. In the event that an individual dies while awaiting COVID-19 test results and a positive result is later confirmed, the death shall be reported to the Department within twenty-four (24) hours of receipt of the positive confirmation. COVID-19 death reporting is required of the physician in charge of the decedent's care, or by the physician in attendance either at

the time of death or immediately before or after, or when appropriate by the local medical examiner, to ensure that such death is reported at once, without delay, and with a sense of urgency by means of rapid communication to the Department regardless of the day or hour. Death notification can be amended at any time should additional information become available.

Reporting Methods

Healthcare providers in Missouri are asked to complete a standard Disease Case Report (CD-1 Form) for the reporting of **confirmed** and **presumptive** COVID-19 cases. A fully completed and timely submitted CD-1 will help allow for a prompt public health follow-up, and help minimize follow-up requests for additional information. The reporting of **death** in any patient with a positive laboratory test for SARS CoV-2 or clinically diagnosed COVID-19 should also be reported using a CD-1.

If the COVID-19 death is the first report for the case, then only one CD-1 Form is needed to report the COVID-19 case and death; insert "COVID-19 Death" as the disease/condition name and check the corresponding box on the CD-1 Form regarding the death and fill in the date of death. If the case had previously been reported, update and resubmit the original CD-1 with the disease/condition name amended to "COVID-19 Death", check the corresponding box noting death, and include the date of death.

Please consider the following options for the timely submission of completed CD-1 reports for confirmed cases, suspected cases, and deaths of COVID-19:

Fax submissions:
As noted on the CD-1, these can be submitted via fax to 573-751-6417. Please note that this fax line experiences high volume during normal business hours.

SFTP:
For providers that would like to submit reports via Secure File Transfer Protocol (SFTP), please call 573-526-5271. The SFTP option functions as a secure online folder where files may be submitted with no wait. In order to use this option, at least one contact e-mail address for the submitting organization must be provided. Further instructions will be sent to the indicated e-mail address(es) once an account is set up for the organization.

Phone:
For single COVID-19 death reports, providers have the option to call the Missouri COVID-19 Hotline at 877-435-8411 and convey information verbally to an operator who will complete the CD-1 for the provider. When utilizing this method of reporting, please choose option 2 at the prompt.

General questions about COVID-19 reporting should be directed to DHSS' Bureau of Reportable Disease Informatics at 573-526-5271.

References:

Dual Reporting of Negative COVID-19 Lab Results:
https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/pdf/waiver-dual-reporting-of-negative-results.pdf

Reporting Death Associated with SARS CoV-2 or Clinically Diagnosed COVID-19:
https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/pdf/report-of-covid-19-death.pdf

Reporting of COVID-19 Lab Results:
https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/pdf/waiver-reporting-of-covid-19-lab-results.pdf

Missouri Department of Health & Senior Services

Health Update:

Update: Interim Guidance for Implementing Safety Practices for Critical Infrastructure Workers Who May Have Had Exposure to a Person with Suspected or Confirmed COVID-19

April 9, 2020

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Health Update
April 9, 2020

FROM: **RANDALL W. WILLIAMS, MD, FACOG**
DIRECTOR

SUBJECT: **Update: Interim Guidance for Implementing Safety Practices for Critical Infrastructure Workers Who May Have Had Exposure to a Person with Suspected or Confirmed COVID-19**

*****Missouri healthcare providers and public health practitioners: Please contact your local public health agency or the Missouri Department of Health and Senior Services (DHSS), Bureau of Communicable Disease Control and Prevention (BCDCP) at 573-751-6113 with questions regarding this Update.*****

To ensure continuity of operations of essential functions, CDC advises that critical infrastructure workers may be permitted to continue work following potential exposure to COVID-19, provided they remain asymptomatic and additional precautions are implemented to protect them and the community.

A potential exposure means being a household contact or having close contact within 6 feet of an individual with confirmed or suspected COVID-19. The timeframe for having contact with an individual includes the period of time of 48 hours before the individual became symptomatic.

Critical Infrastructure workers who have had an exposure but remain asymptomatic should adhere to the following practices prior to and during their work shift:

- Pre-Screen: Employers should measure the employee's temperature and assess symptoms prior to them starting work. Ideally, temperature checks should happen before the individual enters the facility.
- Regular Monitoring: As long as the employee doesn't have a temperature or symptoms, they should self-monitor under the supervision of their employer's occupational health program.
- Wear a Mask: The employee should wear a face mask at all times while in the workplace for 14 days after last exposure. Employers can issue facemasks or can approve employees' supplied cloth face coverings in the event of shortages.
- Social Distance: The employee should maintain 6 feet and practice social distancing as work duties permit in the workplace.
- Disinfect and Clean work spaces: Clean and disinfect all areas such as offices, bathrooms, common areas, shared electronic equipment routinely.

If the employee becomes sick during the day, they should be sent home immediately. Surfaces in their workspace should be cleaned and disinfected. Information on persons who had contact with the ill employee during the time the employee had symptoms and 2 days prior to symptoms should be compiled. Others at the facility with close contact within 6 feet of the employee during this time would be considered exposed.

INTERIM GUIDANCE
This interim guidance pertains to critical infrastructure workers, including personnel in 16 different sectors of work including:

- Federal, state, & local law enforcement
- 911 call center employees
- Fusion Center employees
- Hazardous material responders from government and the private sector
- Janitorial staff and other custodial staff
- Workers – including contracted vendors – in food and agriculture, critical manufacturing, informational technology, transportation, energy and government facilities

ADDITIONAL CONSIDERATIONS

- Employees should not share headsets or other objects that are near mouth or nose.
- Employers should increase the frequency of cleaning commonly touched surfaces.
- Employees and employers should consider pilot testing the use of face masks to ensure they do not interfere with work assignments.
- Employers should work with facility maintenance staff to increase air exchanges in room.
- Employees should physically distance when they take breaks together. Stagger breaks and don't congregate in the break room, and don't share food or utensils.

Employers should implement the recommendations in the Interim Guidance for Businesses and Employers to Plan and Respond to Coronavirus Disease 2019 to help prevent and slow the spread of COVID-19 in the workplace.

Additional information about identifying critical infrastructure during COVID-19 can be found on the DHS CISA website or the CDC's specific First Responder Guidance page.

References:
Interim Guidance for Implementing Safety Practices for Critical Infrastructure Workers Who May Have Had Exposure to a Person with Suspected or Confirmed COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/downloads/critical-workers-implementing-safety-practices.pdf

Missouri Department of Health & Senior Services

Health Update:

Update: COVID-19 Interim Case Definition and Reporting Information for Healthcare Providers

April 10, 2020

This document will be updated as new information becomes available. The current version can always be viewed at http://www.health.mo.gov.

The Missouri Department of Health & Senior Services (DHSS) is now using four types of documents to provide important information to medical and public health professionals, and to other interested persons:

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Health Update
April 10, 2020

FROM: **RANDALL W. WILLIAMS, MD, FACOG**
DIRECTOR

SUBJECT: **Update: COVID-19 Interim Case Definition and Reporting Information for Healthcare Providers**

On Sunday, April 5, 2020, the interim position statement entitled "Standardized surveillance case definition and national notification for 2019 novel coronavirus disease (COVID-19)" was approved. This includes standardized criteria for case identification and classification for COVID-19, including asymptomatic infections caused by SARS-CoV-2. The case definition was developed by the Council of State and Territorial Epidemiologists (CSTE), the Association of Public Health Laboratories (APHL), and the Centers for Disease Control and Prevention (CDC). The CSTE position statement is available here, and a quick reference chart is included as part of this Health Update (page 3).

Though the case definition is meant for public health surveillance purposes, both probable and confirmed cases investigations should follow the same guidelines regarding self-isolation and quarantine for close contacts as advised by public health authorities. All individuals with pending COVID-19 tests should be advised to self-isolate at least until the test results are received. Additionally, household and close contacts may be required to self-quarantine, dependent on their status as a critical infrastructure worker. See *CDC Interim Guidance for Implementing Safety Practices for Critical Infrastructure Workers Who May Have Had Exposure to a Person with Suspected or Confirmed COVID-19.*

Required Case and Associated Data Reporting

During this unprecedented public health emergency, ensuring accurate and timely surveillance is more important than ever. Without critical case information provided from healthcare partners, the COVID-19 response may be delayed or improperly targeted outside of geographic areas that most need resources.

Healthcare providers are required to report both suspected and confirmed COVID-19 cases to the Missouri Department of Health and Senior Services (DHSS), as described in the April 6, 2020 Health Update, *Reporting COVID-19 Cases,* (https://health.mo.gov/emergencies/ert/alertsadvisories/pdf/update4620.pdf). **Note: Only single, COVID-19 death reports** should be communicated to DHSS via phone as described in this document.

Due to the high volume of case reports, COVID-19 case reports should be transmitted to DHSS using the other methods of communication listed in the April 6, 2020 Health Update.

Required elements for case reporting, which are included in the DHSS CD-1 form (https://health.mo.gov/living/healthcondiseases/communicable/communicabledisease/cdmanual/pdf/CD-1.pdf), are outlined in 19 CSR 20-20.020 (https://www.sos.mo.gov/cmsimages/adrules/csr/current/19csr/19c20-20.pdf). These include:

- Patient name
- Home address with zip code
- Date of Birth
- Age
- Sex
- Race
- Home phone number
- Name of Disease
- Condition or finding diagnosed or suspected
- Date of onset of illness
- Name and address of treating facility (if any)
- Name and office address of attending physician
- Any appropriate laboratory results

*****Missouri healthcare providers and public health practitioners: Please contact your local public health agency or the Missouri Department of Health and Senior Services (DHSS), Bureau of Communicable Disease Control and Prevention (BCDCP) at 573-751-6113 with questions regarding this Update.*****

COVID-19 Case Definition

Updated April 8, 2020

Public Health COVID-19 Case Classifications	
Confirmed	Meets confirmatory laboratory evidence.
Probable	Any of the following three options: • Meets clinical criteria **AND** epidemiologic evidence with no confirmatory laboratory testing performed for COVID-19. • Meets presumptive laboratory evidence **AND** either clinical criteria **OR** epidemiologic evidence. • Meets vital records criteria with no confirmatory laboratory testing performed for COVID-19.
Classification Considerations	
Clinical Criteria	At least two of the following symptoms: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, new olfactory and taste disorder(s) **OR** At least one of the following symptoms: cough, shortness of breath, or difficulty breathing **OR** Severe respiratory illness with at least one of the following: Clinical or radiographic evidence of pneumonia Acute respiratory distress syndrome (ARDS). **AND** No alternative more likely diagnosis.
Laboratory Criteria Laboratory evidence using a method approved or authorized by the FDA or designated authority	***Confirmatory*** laboratory evidence: Detection of SARS-CoV-2 RNA in a clinical specimen using a molecular amplification detection test ***Presumptive*** laboratory evidence: Detection of specific antigen in a clinical specimen Detection of specific antibody in serum, plasma, or whole blood indicative of a new or recent infection*
Epidemiologic Linkage One or more of the following exposures in the 14 days before onset of symptoms:	• Close contact** with a confirmed or probable case of COVID-19 disease; • Close contact** with a person with: o clinically compatible illness **AND** o linkage to a confirmed case of COVID-19 disease. • Travel to or residence in an area with sustained, ongoing community transmission of SARS-CoV-2. • Member of a risk cohort as defined by public health authorities during an outbreak.
Vital Records Criteria for Reporting	A death certificate that lists COVID-19 disease or SARS-CoV-2 as a cause of death or a significant condition contributing to death.

*serologic methods for diagnosis are currently being defined

**Close contact is defined as being within 6 feet for at least a period of 10 minutes to 30 minutes or more depending upon the exposure. In healthcare settings, this may be defined as exposures of greater than a few minutes or more. Data are insufficient to precisely define the duration of exposure that constitutes prolonged exposure and thus a close contact.

Missouri Department of Health & Senior Services

Health Update:

Update: New Criteria to Guide Evaluation and Laboratory Testing for COVID-19 at the Missouri State Public Health Laboratory

April 22, 2020

This document will be updated as new information becomes available. The current version can always be viewed at http://www.health.mo.gov.

The Missouri Department of Health & Senior Services (DHSS) is now using four types of documents to provide important information to medical and public health professionals, and to other interested persons:

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Health Update
April 22, 2020

FROM: RANDALL W. WILLIAMS, MD, FACOG
DIRECTOR

SUBJECT: Update: New Criteria to Guide Evaluation and Laboratory Testing for COVID-19 at the Missouri State Public Health Laboratory

COVID-19 diagnostic testing is available through the Missouri State Public Health Laboratory (SPHL) for individuals meeting the criteria included in the appendices to this Health Update. The additional included algorithm is being used by our call center to determine if testing for COVID-19 by the State Public Health Laboratory will be approved.

Please note that some of the initial decision making will require that the patient be evaluated by a healthcare provider. Requests for testing approval must come from a healthcare provider, not the patient or patient's family member. To request testing for patients that meet one of these criteria, please contact your local public health agency or the Missouri Coronavirus Information hotline at 877-435-8411 and select Option 2.

For individuals not meeting DHSS criteria for testing, providers may pursue private laboratory testing. Testing through private laboratories does not require DHSS approval.

Test Types and Their Uses

Currently, the COVID-19 testing at the SPHL includes solely **PCR**. This testing detects the presence of COVID-19 RNA in the clinical specimen, and indicates a likely current infection of COVID-19. Providers should be aware that some patients may shed virus for several weeks, the maximum of which is still being studied. For public health surveillance purposes, PCR testing is considered confirmatory.

Several laboratories are expected to begin offering **serological** testing in the near future, and providers may already be ordering this type of test for their patients. This type of testing detects the presence of antibodies in a person who has previously been exposed to the virus that causes COVID-19 and is not useful for determining if the patient is currently infectious, or if person has developed immunity.

Isolation for Patients Awaiting Test Results

Local public health agencies routinely follow up with individuals that are identified as confirmed or probable COVID-19 cases to ensure appropriate isolation, but this disease control activity depends on test results and case reports as their notification mechanism. Individuals being testing for COVID-19 should be considered suspect cases and asked to self-isolate at least until test results are received. This is an important disease control step that healthcare providers can take to help control the spread of COVID-19 in our communities.

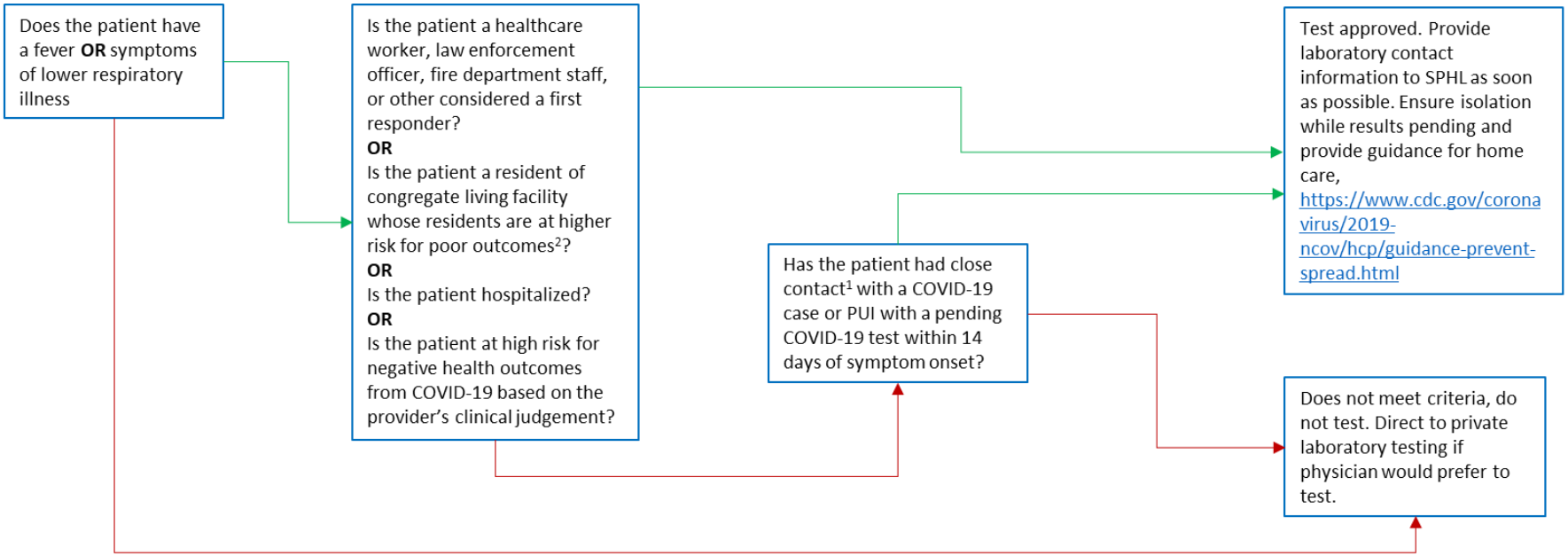
Patients can be provided educational materials to help them understand what self-isolation means: https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf.

Additionally, patients can be provided information about how to protect their families while their test is pending: https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/care-for-someone.html

Risk Groups to be Approved for COVID-19 Testing by DHSS	
Risk Group	**Definitions and Further Information**
Symptomatic[1] close contacts to a suspect COVID-19 patient with pending laboratory testing or laboratory-confirmed COVID-19 patient	Close contact is defined as— a) being within approximately 6 feet (2 meters) of a COVID-19 case for a prolonged period of time; close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case *– or –* b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on) If such contact occurs while not wearing recommended personal protective equipment or PPE (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection), criteria for PUI consideration are met.
Symptomatic[1] healthcare workers, law enforcement officers, fire department staff, and others who are considered first responders	Contact with a suspected or confirmed case is not required for these individuals.
Symptomatic[1] residents of congregate living facilities whose residents are at higher risk for poor outcomes	Those at higher risk for poor outcomes can include older adults and individuals with chronic medical conditions and/or an immunocompromised state. Note: In some facilities with a large number of cases that indicate late detection of an outbreak or infection control lapses, testing for all staff and residents MAY be approved on a case-by-case basis in consultation with state epidemiology staff or DHSS Director.
Symptomatic[1] hospitalized patients who have signs and symptoms compatible with COVID-19	Testing for these individuals should be used to inform decisions regarding infection control.
Symptomatic[1] patients who are at high risk for negative health outcomes from COVID-19	Risk for negative health outcomes is based on the provider's clinical judgement.

Note: Postmortem testing can be approved through the Missouri State Public Health Laboratory if an individual would have met a criterion above prior to their death.

[1]Symptoms may include any of the following: fever, cough, shortness of breath or difficulty breathing, chills, repeated shaking with chills, muscle pain, headache, sore throat, new loss of taste or smell, or any other relevant symptoms per medical provider judgement



Clearance Testing: Approve clearance testing for individuals required to use test-based method to return to at-risk group setting as resident or employee, such as long-term care, corrections, adult group homes, healthcare facilities, etc. Clearance testing is 2 consecutive negative tests where specimens are taken at least 24 hours apart. ONLY FOR PREVIOUSLY CONFIRMED CASES

[1]Close contact is defined as—

a) being within approximately 6 feet (2 meters) of a COVID-19 case for a prolonged period of time; close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case

– or –

b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on)

If such contact occurs while not wearing recommended personal protective equipment or PPE (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection), criteria for PUI consideration are met.

[2]Those at higher risk for poor outcomes can include older adults and individuals with chronic medical conditions and/or an immunocompromised state (e.g., diabetes, heart disease, receiving immunosuppressive medications, chronic lung disease, chronic kidney disease).

Note: Postmortem testing can be approved through the Missouri State Public Health Laboratory if an individual would have met a criterion above prior to their death.

Missouri Department of Health & Senior Services

Health Update:

Update: COVID-19 Testing Expansion and Serology Reporting

April 30, 2020

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FROM: RANDALL W. WILLIAMS, MD, FACOG
DIRECTOR

SUBJECT: CORRECTED EDITION: Update- COVID-19 Testing Expansion and Serology Reporting

The Department of Health and Senior Services is issuing this health update notification to Missouri clinicians and physicians relating to expanded COVID-19 testing availability within the state. **Diagnostic PCR and serological COVID-19 testing is encouraged for asymptomatic persons when deemed appropriate clinically or for surveillance.**

COVID-19 PCR testing

As availability of diagnostic PCR testing and rapid testing methodologies continue to increase through the private marketplace, DHSS is advising clinicians to consider a wider scope of testing utilization for Missouri citizens as part of Governor Parson's *Show Me Strong Recovery Plan*.

As a reminder, last week DHSS expanded testing approval criteria for COVID-19 PCR tests conducted at the Missouri State Public Health Laboratory. A quick reference of the current criteria can be found at this link:
https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus-lpha/pdf/mo-pui-guidance.pdf

COVID-19 serological testing and reporting

Serological and diagnostic PCR results are reportable to DHSS within 24 hours in order to allow timely public health investigation. Providers and laboratories should report both test types to DHSS as was previously announced. Links to reporting guidance Health Updates are provided here for ease of access:
https://health.mo.gov/emergencies/ert/alertsadvisories/pdf/update4620.pdf

https://health.mo.gov/emergencies/ert/alertsadvisories/pdf/update41020.pdf

Providers should be aware that serological testing is not considered diagnostic for COVID-19 disease. Serological testing detects antibodies that likely resulted from an infection with SARS-CoV- 2, or possibly a related coronavirus. For more information on the use of COVID-19 serological testing, please see the Infectious Disease Society of America's *IDSA COVID-19 Antibody Testing Primer*: https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf.

Missouri Department of Health & Senior Services

Health Update:

Antigen Testing for COVID-19

June 3, 2020

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Health Update
June 3, 2020

FROM: RANDALL W. WILLIAMS, MD, FACOG
DIRECTOR

SUBJECT: Antigen Testing for COVID-19

The Missouri Department of Health and Senior Services is issuing this health update notification to Missouri clinicians, physicians, and laboratories related to the use and reporting of antigen tests for SARS CoV-2, the virus that causes COVID-19. Providers and laboratories should immediately report all results from antigen tests for SARS CoV-2 to DHSS in accordance with established rules and waivers for the reporting of COVID-19 in the state of Missouri. Reporting guidance was included in a prior Health Update released on April 6, 2020, available at https://health.mo.gov/emergencies/ert/alertsadvisories/pdf/update4620.pdf.

Antigen Tests

On May 8, 2020, the U.S. Food and Drug Administration (FDA) issued the first emergency use authorization (EUA) for an antigen test for COVID-19. Antigen tests are new type of diagnostic test designed for rapid detection SARS CoV-2. Although a new diagnostic tool for COVID-19, antigen tests are routinely used for the diagnosis of other infections including influenza. Antigen tests are considered diagnostic tests and work by quickly detecting fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs. Antigen tests are an important addition to the overall response against COVID-19 and the FDA expects many more antigen tests to receive EUA approval. Additional information regarding the EUA approved antigen test is available from the FDA at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-antigen-test-help-rapid-detection-virus-causes

The advantages of antigen tests generally include the lower cost to produce and the speed of the test. Antigen test results are usually available in minutes. However, it is important to note there are limitations. Antigen tests may not detect all active infections. Antigen tests are very specific for the virus, but are not as sensitive as molecular PCR tests. This means that positive results from antigen tests are highly accurate, but there is a higher chance of false negatives, so negative results do not rule out infection. With this in mind, negative results from an antigen test may need to be confirmed with a PCR test prior to making treatment decisions or to prevent the possible spread of the virus due to a false negative.

Antigen tests results are included in the national reporting case definition developed by the Council of State and Territorial Epidemiologists (CSTE), the Association of Public Health Laboratories (APHL), and the Centers for Disease Control and Prevention (CDC). In accordance with the case definition, results from

antigen and antibody tests are considered presumptive laboratory evidence. Results from PCR and other approved molecular amplification detection tests are considered confirmatory laboratory evidence. Additional information on case classification and the national reporting case definition was included in the Health Update released on April 10, 2020, available at https://health.mo.gov/emergencies/ert/alertsadvisories/pdf/update41020.pdf

General questions about COVID-19 reporting should be directed to DHSS' Bureau of Reportable Disease Informatics at 573-526-5271.

Missouri Department of Health & Senior Services

Health Update:

Discontinuation of Isolation for Persons with COVID-19

July 27, 2020

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Health Update
July 27, 2020

FROM: **RANDALL W. WILLIAMS, MD, FACOG**
DIRECTOR

SUBJECT: **Discontinuation of Isolation for Persons with COVID-19**

The Missouri Department of Health and Senior Services (DHSS) is issuing this health update notification to Missouri clinicians, physicians, public health practitioners, employers and the public regarding the discontinuation of isolation for persons with COVID-19. The guidance included is in accordance with updates to guidance issued by the Centers for Disease Control and Prevention (CDC) released on July 17, 2020. A summary of current evidence and rationale for these changes is described by CDC in a decision memo "Duration of Isolation and Precautions for Adults with COVID-19", is available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.

Assessment

Available data indicate that persons with mild to moderate COVID-19 remain infectious no longer than 10 days after symptom onset. Persons with more severe to critical illness or are severely immunocompromised likely remain infectious no longer than 20 days after symptom onset. Recovered persons can continue to shed detectable SARS-CoV-2 RNA in upper respiratory specimens for up to 3 months after illness onset, albeit at concentrations considerably lower than during illness, in ranges where replication-competent virus has not been reliably recovered and infectiousness is unlikely. The etiology of this persistently detectable SARS-CoV-2 RNA has yet to be determined. Studies have not found evidence that clinically recovered persons with persistence of viral RNA have transmitted SARS-CoV-2 to others. These findings strengthen the justification for relying on a symptom based, rather than test-based strategy for ending isolation of these patients, so that persons who are by current evidence no longer infectious are not kept unnecessarily isolated and excluded from work or other responsibilities.

Reinfection with SARS-CoV-2 has not yet been definitively confirmed in any recovered persons to date. If, and if so when, persons can be reinfected with SARS-CoV-2 remains unknown and is a subject of investigation. Persons infected with related endemic human betacoronavirus appear to become susceptible again at around 90 days after onset of infection. Thus, for persons recovered from SARS-CoV-2 infection, a positive PCR during the 90 days after illness onset more likely represents persistent shedding of viral RNA than reinfection.

- If such a person remains asymptomatic during this 90-day period, then any re-testing is unlikely to yield useful information, even if the person had close contact with an infected person.
- If such a person becomes symptomatic during this 90-day period and an evaluation fails to identify a diagnosis other than SARS-CoV-2 infection (e.g., influenza), then the person may warrant evaluation for SARS-CoV-2 reinfection in consultation with an infectious disease or infection control expert. Isolation may be warranted during this evaluation, particularly if symptoms developed after close contact with an infected person.

Correlates of immunity to SARS-CoV-2 infection have not been established. Specifically, the utility of serologic testing to establish the absence or presence of infection or reinfection remains undefined.

Recommendations:

The recommendations below are based on the best information available in mid-July 2020 and reflect the realities of an evolving pandemic. Even for pathogens for which many years of data are available, it may not be possible to establish recommendations that ensure 100% of persons who are shedding replication-competent virus remain isolated. CDC and DHSS will continue to closely monitor the evolving science for information that would warrant reconsideration of these recommendations. For additional recommendations see the additional references in the healthcare and non-healthcare sections provided below.

1. **Duration of isolation and precautions**
   - For most persons with COVID-19 illness, isolation and precautions can generally be discontinued 10 days *after symptom onset*[1] and resolution of fever for at least 24 hours, without the use of fever-reducing medications, and with improvement of other symptoms.
   - A limited number of persons with severe illness[2] may produce replication-competent virus beyond 10 days that may warrant extending duration of isolation and precautions for up to 20 days after symptom onset; consider consultation with infection control experts.
   - For persons who never develop symptoms, isolation and other precautions can be discontinued 10 days *after the date of their first positive RT-PCR test for SARS-CoV-2 RNA.*

2. **Role of PCR testing[3] to discontinue isolation or precautions**
   - For persons who are severely immunocompromised[4], a test-based strategy could be considered in consultation with infectious diseases experts.
   - For all others, a test-based strategy is no longer recommended except to discontinue isolation or precautions earlier than would occur under the strategy outlined in Part 1, above.

3. **Role of PCR testing[3] after discontinuation of isolation or precautions**
   - For persons previously diagnosed with symptomatic COVID-19 who remain asymptomatic after recovery, retesting is not recommended within 3 months after the date of symptom onset for the initial COVID-19 infection. In addition, quarantine is not recommended in the event of close contact with an infected person.

- For persons who develop new symptoms consistent with COVID-19 during the 3 months after the date of initial symptom onset, if an alternative etiology cannot be identified by a provider, then the person may warrant retesting; consultation with infectious disease or infection control experts is recommended. Isolation may be considered during this evaluation based on consultation with an infection control expert, especially in the event symptoms develop within 14 days after close contact with an infected person.
- For persons who never developed symptoms, the date of first positive RT-PCR test for SARS-CoV-2 RNA should be used in place of the date of symptom onset.

4. **Role of serologic testing**
   - Serologic testing should not be used to establish the presence or absence of SARS-CoV-2 infection or reinfection.

1. *Symptom onset is defined as the date on which symptoms first began, including non-respiratory symptoms.*

2. *An option for defining the severity of illness involves definitions as provide by The National Institutes of Health (NIH) COVID-19 Treatment Guidelines. The NIH Guidance was not developed to inform decisions about duration of Transmission-Based Precautions. However, the conservative approach described in this guidance can be informed by NIH. The highest level of illness severity experienced by the patient at any point in their clinical course should be used when determining the duration of Transmission-Based Precautions.*

   Mild Illness: Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain) without shortness of breath, dyspnea, or abnormal chest imaging.

   Moderate Illness: Individuals who have evidence of lower respiratory disease by clinical assessment or imaging, and a saturation of oxygen (SpO2) ≥94% on room air at sea level.

   Severe Illness: Individuals who have respiratory frequency >30 breaths per minute, SpO2 <94% on room air at sea level (or, for patients with chronic hypoxemia, a decrease from baseline of >3%), ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) <300 mmHg, or lung infiltrates >50%.

   Critical Illness: Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

In pediatric patients, radiographic abnormalities are common and, for the most part, should not be used as the sole criteria to define COVID-19 illness category. Normal values for respiratory rate also vary with age in children, thus hypoxia should be the primary criterion to define severe illness, especially in younger children.

3. *PCR testing is defined as the use of an RT-PCR assay to detect the presence of SARS-CoV-2 RNA.*

4. *Based on available data in the medical literature and ID expert opinion, severely immunocompromised patients include:*
   - *Those with neutropenia (ANC or WBC < 500/mm3)*

- *Those with leukemia/lymphoma undergoing chemotherapy*
- *HIV patients with CD4 count <200*
- *Transplant patients who have undergone solid organ or allogeneic stem cell transplant on immunosuppressive therapy or who have GVHD*
- *Transplant patients who have undergone autologous transplant less than 6 months from transplant*
- *Those on high dose steroids steroid dose of either >2 mg/kg of body weight or ≥20 mg per day of prednisone or equivalent in people who weigh >10 kg, when administered for ≥2 weeks*

Please note: Patients with autoimmune diseases requiring treatment with immunosuppressive medications such as TNF alpha inhibitors, should be reviews with ID specialists for further direction.

Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance) available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html. Updates to the previous guidance includes the following:

- Except for rare situations, a test-based strategy is no longer recommended to determine when to discontinue Transmission-Based Precautions.
- For patients with severe to critical illness or who are severely immunocompromised1, the recommended duration for Transmission-Based Precautions was extended to 20 days after symptom onset (or, for asymptomatic severely immunocompromised1 patients, 20 days after their initial positive SARS-CoV-2 diagnostic test).
- Other symptom-based criteria were modified as follows: ◦Changed from "at least 72 hours" to "at least 24 hours" have passed since last fever without the use of fever-reducing medications.
- Changed from "improvement in respiratory symptoms" to "improvement in symptoms" to address expanding list of symptoms associated with COVID-19.

Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings is available https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html. Updates to the previous guidance includes the following:

- A test-based strategy is no longer recommended to determine when to discontinue home isolation, except in certain circumstances.
- Symptom-based criteria were modified as follows: ◦Changed from "at least 72 hours" to "at least 24 hours" have passed since last fever without the use of fever-reducing medications.
- Changed from "improvement in respiratory symptoms" to "improvement in symptoms" to address expanding list of symptoms associated with COVID-19.
- For patients with severe illness, duration of isolation for up to 20 days after symptom onset may be warranted. Consider consultation with infection control experts.
- For persons who never develop symptoms, isolation and other precautions can be discontinued 10 days after the date of their first positive RT-PCR test for SARS-CoV-2 RNA.

Missouri healthcare providers and public health practitioners: Please contact your local public health agency or the Missouri Department of Health and Senior Services' (DHSS') Bureau of Communicable Disease Control and Prevention at 573-751-6113 or 800-392-0272 (24/7) with questions regarding this Alert.

Missouri Department of Health & Senior Services

Health Update:

Recommended Measures to Limit False Positive Results with COVID-19 Antigen Tests

November 9, 2020

This document will be updated as new information becomes available. The current version can always be viewed at http://www.health.mo.gov.

The Missouri Department of Health & Senior Services (DHSS) is now using four types of documents to provide important information to medical and public health professionals, and to other interested persons:

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require

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Health Update
November 9, 2020

FROM: **RANDALL W. WILLIAMS, MD, FACOG**
DIRECTOR

SUBJECT: **Update: Recommended Measures to Limit False Positive Results with COVID-19 Antigen Tests**

The Missouri Department of Health and Senior Services (DHSS) is issuing this health update notification to Missouri clinicians, physicians, laboratories, congregate care facilities, and k-12 schools regarding the importance of following the manufacturer's instructions when using antigen tests for COVID-19. The U.S. Food and Drug Administration (FDA) issued a **letter of concern** regarding the potential for **false positive** results with antigen tests for the rapid detection of SARS-CoV-2, the virus that causes COIVD-19. Failure to strictly adhere to the manufacturer's instructions and the following guidance provided by the FDA may lead to an increase in false positive test results, which can have a substantial negative impact on the community.

There are risks of false positive results with all laboratory tests. Laboratories should expect some false positive results to occur even when very accurate tests are used for screening large populations with a low prevalence of infection. Health care providers and clinical laboratory staff can help ensure accurate reporting of test results by following the authorized instructions for use of a test and key steps in the testing process as recommended by the Centers for Disease Control and Prevention (CDC), including routine follow-up testing (reflex testing) with a molecular assay when appropriate, and by considering the expected occurrence of false positive results when interpreting test results in their patient populations.

DHSS recommends clinical laboratory staff and health care providers who use antigen tests for the rapid detection of SARS-CoV-2 consider the following recommendations from the FDA, including, but not limited to:

- Follow the manufacturer's instructions for use, typically found in the package insert, when performing the test and reading test results. If you no longer have the package insert the authorized instructions for use for each test can also be found on the FDA's COVID-19 IVD EUA webpage.
    - For example, the package insert for tests include instructions for handling of the test cartridge/card, such as ensuring it is not stored open prior to use. If the test components are not stored properly, this can affect the performance of the test.

The package insert for tests also includes instructions about reading the test results, including the appropriate time to read the results. **Reading the test *before or after* the specified time could result in false positive or false negative results.**

- Be aware that processing multiple specimens in batch mode may make it more challenging to ensure the correct incubation time for each specimen. Refer to the package insert and ensure proper timing for each specimen when processing the specimen in the test device and reading the results.
- Be careful to minimize the risks of cross-contamination when testing patient specimens, which can cause false positive results. Insufficient cleaning of the workspace, insufficient disinfection of the instrument, or inappropriate use of protective equipment (for example, failing to change gloves between patients) can increase the risk of cross-contamination between specimens with subsequent false positive results. Consider the CDC guidance for changing gloves and cleaning work area between specimen handling and processing.
- Consider the CDC's recommendations when using antigen testing in nursing homes and other settings. For positive results, especially in low incidence counties, consider performing confirmatory RT-PCR test within 48 hours.
- Remember that positive predictive value (PPV) varies with disease prevalence when interpreting results from diagnostic tests.
- Consider positive results in combination with clinical observations, patient history, and epidemiological information.

The FDA will continue to monitor the use of rapid antigen test platforms and will keep clinical laboratory staff, health care providers, manufacturers, and the public informed of new or additional information. DHSS will promptly inform all Missouri users of these testing platforms as developments occur.

Missouri healthcare providers, public health practitioners and users of rapid antigen testing platforms, please contact your local public health agency or the Missouri Department of Health and Senior Services' (DHSS') Bureau of Communicable Disease Control and Prevention at 573-751-6113 or 800-392-0272 (24/7) with questions regarding this Guidance. Technical questions regarding the use of rapid antigen test platforms should be directed to Russ Drury, Missouri State Public Health Laboratory at Russ.Drury@health.mo.gov